

REMARKS

I. Claim Status

Claims 1-18 are currently pending. Claims 3-6, 8, and 11-12 have been withdrawn from consideration. Claims 1, 2, 7, 9-10, and 13-15 are rejected. Claims 1-8 have been amended herein. Those amendments are supported in the specification and claims as originally filed and do not add new matter. Claims 16-18 have been added. Those claims are supported throughout the specification, e.g., page 5, lines 3-11. Accordingly, no new matter is added by those claims. In addition, those claims fall within Applicants' elected subject matter.

II. Restriction Requirement

Applicants want to correct the record with respect to elected subject matter. According to Applicants' Response to Restriction Requirement dated January 28, 2009, ("Response"), Applicants elected psychotic cognitive impairment from Group A (various symptoms) and schizophrenia from Group B (disorders or conditions). See Response at 1-2. Those elections are not "compound/compositions, method of treatment and process" elections as attributed to Applicants by the Examiner. See Non-final Office Action dated March 19, 2009 ("Office Action") at 3.

Moreover, Applicants did not provide the reason "since the EPO (in the PCT counter part of this application) is a competent search authority and they were able to search the invention . . ." for the impropriety of the species election requirement. See *id.* Instead, Applicants argued that the Office was impermissibly using U.S. restriction practice instead of the appropriate standard prescribed for national stage applications under § 371. See Response at 2. Applicants asserted and continue to maintain the position that the presently pending claims include a uniting technical feature (*see id.*),

and that there is a reasonable similarity among the Markush group members, precluding a species election requirement (see *id.* at 3).

III. 35 U.S.C. § 103(a) Rejection

The Examiner rejected claims 1, 2, 7, 9-10, and 13-15 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent Nos. 5,902,807 to Haapalinna et al. (“Haapalinna”) and 5,492,907 to Pickar et al. (“Pickar”) in view of Ludewig, K. et al., “Impaired sensorimotor gating in schizophrenia with deficit and with nondeficit syndrome,” *Swiss Med. Wkly.* (2002) 13:159-165 (“Ludewig”). Applicants respectfully traverse this rejection.

The Examiner has failed to establish a *prima facie* case of obviousness for at least the reasons that 1) one of ordinary skill in the art would have been led away from combining the teachings of Haapalinna and Pickar and 2) the combined teachings of Haapalinna and Pickar would not teach or suggest all of the limitations of the present claims since Ludewig is not prior art to the present application.

Haapalinna discloses methods for treating mental illness induced by stress by administering **specific** alpha-2C-adrenoceptor antagonists alone or in combination with an anxiolytic, antidepressive, or antipsychotic compound. See e.g., Haapalinna, col. 2., lines 34-3. As noted by Haapalinna, “the alpha-2C-adrenoreceptor appears to be distributed along the limbic system (a complex brain area related to affects and other mental functions),” such as **stress**. Accordingly, Haapalinna hypothesized that a **behavioral** response associated with alpha-2C selective adrenoceptor antagonists would be different from that associated with non-specific alpha-2-adrenoceptor antagonists. *Id.* at col. 1, lines 33-36.

Haapalinna thus studied “the role of alpha2C-adrenoreceptor in animal models reflecting **stress propagation-induced behavioural changes**.” Col. 3, lines 61-63 (emphasis added). Those studies led Haapalinna to conclude, *inter alia*, that “the selective alpha-2C-adrenoreceptor antagonist but not the non-selective alpha-2-adrenoceptor antagonist prevented propagation of stress-induced behavioural despair” (col. 6, lines 14), that “[u]sing the alpha-2C-adrenoceptor selective dose..., this drug had response similar to other anxiolytic agents.... [but], similar to other typical non-selective alpha-2-adrenoceptor antagonists, [the non-selective drug tested] did not provide any anxiolytic response...” (col. 7, lines 12-17), and that non-selective alpha-2C-adrenoceptor antagonists potentiate neophobic stress whereas the tested selective alpha-2C-adrenoceptor antagonist does not and, in fact, augments exploratory behavior as anxiolytics do (col. 7, lines 41-49). Accordingly, Haapalinna concluded that **specific** alpha-2C-adrenoceptor antagonists alone or in combination with an anxiolytic, antidepressive, or antipsychotic compound could be used for treating mental illness induced by stress, whereas non-specific alpha-2C-adrenoceptor antagonists could not.

As admitted by the Examiner, however, “Haaplinna does not expressly teach that the treatment is for schizophrenia or sensorimotor gating defects.” Office Action at 5. To cure those defects, the Examiner relies on Pickar and Ludewig, respectively.

Pickar discloses methods for treating serious psychotic mental illnesses (including schizophrenia) using **non-specific** alpha-2-adrenoceptor antagonists, specifically idazoxan, in combination with a D2 dopamine receptor antagonist (otherwise known as typical antipsychotics). See, e.g., Pickar, col. 1, lines 44-63 and lines 10-23. The Examiner concludes that “it would have been obvious to one of ordinary skills [*sic*]

in the art to employ species of α_2 -adrenoceptor to treat schizophrenia as taught by Haapalinna because Haapalinna teaches broadly that ... the species alpha-2C-adrenoceptor is effective in the treatment of mental illness” Office Action at 5-6. Applicants disagree.

As an initial matter, Applicants note that Haapalinna does not “teach[] broadly that ... the species alpha-2C-adrenoceptor is effective in the treatment of mental illness,” as alleged by the Examiner. *Id.* Rather, Haapalinna is focussed on **treating mental illness induced by stress**. And schizophrenia is not induced by stress. Accordingly, the asserted reason for combining the references is factually flawed and does not support a *prima facie* case of obviousness.

Second, “It is improper to combine references where the references teach away from their combination.” M.P.E.P. 2145(X)(D)(2). Here, Pickar’s invention requires the use of a conventional α_2 -adrenoceptor; most preferred is idazoxan. See, e.g., col. 2, lines 64-66. Haapalinna teaches that idazoxan, like yohimbe, is a non-specific alpha-2-adrenoceptor antagonist and that “conventionally antagonists of alpha-2-adrenoceptors, such as yohimbe, have been found to be anxiogenic,” i.e., **cause anxiety**. Col. 1, lines 18-28. Accordingly, one would have been led away from employing a species of α_2 -adrenoceptor disclosed in Pickar in Haapalinna’s invention.

Third, for argument’s sake, even if Haapalinna and Pickar’s teachings were combined, those combined teachings would not teach or suggest each and every limitation of the present claims. In particular, the combination of Haapalinna and Pickar’s teachings would not teach or suggest a method of treatment comprising administering to a mammal in need of treatment for at least one symptom of a disorder

or condition associated with sensorimotor gating deficits, as each of those references is silent with regard to sensorimotor gating deficits. To remedy that deficiency, the Examiner relies on Ludewig. However, Ludewig was published on April 6, 2002, as evidenced by the print-out submitted herewith obtained from Swiss Medical Weekly's archive (http://www.smw.ch/dfe/set_archiv.asp, last accessed on June 18, 2009). The present application claims priority to International Application No. PCT/FI03/00254, filed April 3, 2003, which claims priority to U.S. Provisional Application No. 60/369,323, filed on **April 3, 2002**. Thus, the earliest effective U.S. filing date for this application is April 3, 2002, three days prior to the publication of Ludewig. Consequently, Ludewig is not prior art to the present application and thus cannot be used to support the Office's rejection under § 103.

For at least the reasons above, this rejection should be withdrawn.

New claims 16-18 are not obvious in view of Haapilinna and Pickar for the same reasons as above.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Attachment: http://www.smw.ch/dfe/set_archiv.asp, last accessed on June 18, 2009

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